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EXAMINER

POUS, NATALIE R

ART UNIT PAPER NUMBER

3731

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/642,397	Applicant(s) CHU ET AL.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19,21-35 and 37-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-19, 21-35, 37-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/17/06, 3/30/06, 11/22/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Regarding Anderson

Applicant argues that Anderson does not describe a plurality of curves. Examiner respectfully disagrees. As seen in fig. 2, a small curved portion creates a curve connecting each "linear portion," thus Anderson does teach a plurality of curves.

Applicant's arguments with respect to claims 1-4, 6, 9-14, 17, 19-22, 24, 26-28, 31, 33-38, 40, 43-48, 51, 53, 54, 57-59 and 63 have been considered but are moot in view of the new ground(s) of rejection.

Regarding Giesy

Applicant's arguments filed 8/22/06 have been fully considered but they are not persuasive.

Applicant argues that Giesy does not teach wherein the substantially straight portion is bent at an angle relative to the shaft. Examiner respectfully disagrees. If applicant applies the same logic to the current application, it will be seen that the specification is not enabled. The curved portion is inherently the portion of the shaft adjacent to the substantially straight portion, and thus it would be impossible for the straight portion to be bent with respect to an adjacent portion of the shaft. In accordance with the embodiments of the specification (in particular figs. 14-16), wherein substantially straight portion is (91) is bent with respect to an adjacent portion of the shaft, wherein the straight portion and the shaft portion are connected by a curved portion as seen in figs. 14-16. Thus,

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portion 20e of Giesy is simply the bent portion, allowing for straight portion 20f to be bent with respect to adjacent shaft portion 22. Thus, applicant sustains the prior rejection of claims 1, 8, 13-16, 19, 27-30, 33, 42 and 47-50.

Regarding Raz

Applicant's arguments with respect to claims 1, 2, 5, 7, 13, 18, 19, 20, 23, 25, 27, 32, 33, 36, 39, 41, 47 and 52 with respect to Raz have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7, 9-11, 19, 22, 23, 25, 33-35, 38, 39, 41, 43-45, 53, 56-58 and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenneman et al. (US 6319272).

Regarding Claim 1, Brenneman teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle (310), and a shaft (320) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (fig.

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17), the proximal end of the shaft being attached to the handle (fig. 17) wherein the distal end of the shaft includes a substantially straight portion (389) bent at an angle to an adjacent portion of the shaft (at 320 in fig. 18) , and the substantially straight portion (389) has a length that is less than about 10% of the entire length of the shaft.

Regarding Claim 4, Brenneman teaches the delivery device of claim 1, wherein the substantially straight portion is bent at an angle toward a pubic bone of a patient (fig. 17).

Regarding Claim 5, Brenneman teaches the delivery device of claim 2, wherein the angle relative to the shaft is about 90 degrees (fig. 21).

Regarding Claim 7, Brenneman teaches the delivery device of claim 1, wherein the angle relative to the shaft is less than about 90 degrees (fig. 18).

Regarding Claim 9, Brenneman teaches the delivery device of claim 1, wherein at least one of the curves describes an arc of greater than about 45 degrees (angle between portions 397 and 393).

Regarding Claim 10, Brenneman teaches the delivery device of claim 1, wherein at least one of the plurality of curves describes an arc of greater than about 60 degrees (angle between portions 397 and 393).

Regarding Claim 11, Brenneman teaches the delivery device of claim 1, wherein at least one of the plurality of curves describes an arc of greater than about 90 degrees (angle between portions 397 and 393).

Regarding Claim 19, Brenneman teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a

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handle (310), and a shaft (320) having proximal and distal ends, the proximal end being connected to the handle (fig. 17) and the distal end including a substantially straight portion (338) bent at an angle relative to an adjacent portion of the shaft (at 320 in fig. 18), wherein the substantially straight portion has a length that is less than about 10% of the entire length of the shaft.

Regarding Claim 22, Brenneman teaches the delivery device of claim 19, wherein the substantially straight portion is bent at an angle toward a pubic bone of a patient (fig. 17).

Regarding Claim 23, Brenneman teaches the delivery device of claim 19, wherein the angle relative to the shaft is about 90 degrees (fig. 21).

Regarding Claim 25, Brenneman teaches the delivery device of claim 19, wherein the angle relative to the shaft is less than about 90 degrees (fig. 18).

Regarding Claim 33, Brenneman teaches a delivery system for delivering an implant to an anatomical site in a body of a patient, the system comprising, an implant (348) having first and second ends, and a delivery device comprising a handle (310), and a shaft (320) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length, the proximal end of the shaft being attached to the handle (fig. 17) wherein the distal end of the shaft includes a substantially straight portion (389) bent at an angle relative to an adjacent portion (at 320 in fig. 18), of the shaft, and the substantially straight portion has a length that is less than about 10% of the entire length of the shaft.

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Regarding Claim 34, Brenneman teaches the delivery system of claim 33, wherein the implant includes a sling for treating urinary incontinence (Column 12, proximate lines 28-30).

Regarding Claim 35, Brenneman teaches the delivery system of claim 34, wherein the sling is configured for placement at a midurethral anatomical site in the body of a patient (fig. 17).

Regarding Claim 38, Brenneman teaches the delivery system of claim 35, wherein the substantially straight portion is bent at an angle in a direction toward a pubic bone of a patient (fig. 17).

Regarding Claim 39, Brenneman teaches the delivery device of claim 35, wherein the angle relative to the shaft is about 90 degrees (fig. 21).

Regarding Claim 41, Brenneman teaches the delivery system of claim 35, wherein the angle relative to the shaft is less than about 90 degrees (fig. 17).

Regarding Claim 43, Brenneman teaches the delivery device of claim 33, wherein at least one of the curves describes an arc of greater than about 45 degrees (angle between portions 397 and 393).

Regarding Claim 44, Brenneman teaches the delivery device of claim 33, wherein at least one of the plurality of curves describes an arc of greater than about 60 degrees (angle between portions 397 and 393).

Regarding Claim 45, Brenneman teaches the delivery device of claim 33, wherein at least one of the plurality of curves describes an arc of greater than about 90 degrees (angle between portions 397 and 393).

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Regarding Claim 53, Brenneman teaches a method of delivering an implant to an anatomical site in a body of a patient, the method comprising, inserting into a body of a patient a shaft having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (fig. 17), attaching the distal end of the shaft to a first end of an implant (fig. 18), and positioning the implant at an anatomical site within the body of the patient (fig. 17), wherein the distal end of the shaft includes a substantially straight portion (389) bent at an angle relative to an adjacent portion of the shaft, and the substantially straight portion has a length that is less than about 10% of the entire length of the shaft.

Regarding Claim 56, Brenneman teaches the method of claim 53 comprising inserting the shaft into the body of the patient transvaginally (fig. 17).

Regarding Claim 57, Brenneman teaches the method of claim 53, wherein the implant includes a sling for treating urinary incontinence (Column 12, proximate lines 28-30) and the method includes positioning the sling at a midurethral location (fig. 17).

Regarding Claim 58, Brenneman teaches a method of delivering an implant to an anatomical site in a body of a patient, the method comprising, inserting into a body of a patient a shaft having proximal and distal ends, the proximal end being connected to the handle and the distal end including a substantially straight portion bent at an angle relative to an adjacent portion of the shaft and the substantially straight portion has a length that is less than about 10% of the entire length of the shaft, attaching the distal end of the shaft to a first

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end of an implant (fig. 18), and positioning the implant at an anatomical site within the body of the patient (fig. 17).

Regarding Claim 62, Brenneman teaches the method of claim 58 comprising inserting the shaft into the body of the patient transvaginally (fig. 17).

Regarding Claim 63, Brenneman teaches the method of claim 58, wherein the implant includes a sling for treating urinary incontinence and the method includes positioning the sling at a midurethral location (fig. 17).

Claims 1, 6, 8, 13-16, 18, 19, 24, 27-30, 32, 33, 42 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Giesy et al. (US 5152749).

Regarding Claim 1, Giesy teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle (12), and a shaft (20) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (fig. 7), the proximal end of the shaft being attached to the handle (fig. 2) wherein the distal end of the shaft includes a substantially straight portion (20f) bent at an angle to an adjacent portion of the shaft (22c), and the substantially straight portion (22f) has a length that is less than about 10% of the entire length of the shaft.

Regarding Claim 6, Giesy teaches the delivery device of claim 1, wherein the angle relative to the shaft is greater than about 90 degrees.

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Regarding Claim 8, Giesy teaches the delivery device of claim 1, wherein a most distal one of the plurality of curves includes a concave portion (20e) and a convex portion (20d) and the bend is formed toward the concave portion (fig. 7).

Regarding Claim 13, Giesy teaches the delivery device of claim 1, including a connector (20b) located at the distal end of the shaft for attaching to an end of the implant (40).

Regarding Claim 14, Giesy teaches the delivery device of claim 13, wherein the connector (20b) is formed integral to the shaft (20).

Regarding Claim 15, Giesy teaches the delivery device of claim 14, wherein the connector includes a slot (82) formed in the shaft.

Regarding Claim 16, Giesy teaches the delivery device of claim 14, wherein the slot extends from a surface of the shaft radially (82) into the shaft and axially in a distal direction (83) to form a substantially L- shape.

Regarding Claim 18, Giesy teaches the delivery device of claim 13, wherein the connector includes a receptacle (82) portion for interfitting with a mating connector on the end of the implant.

Regarding Claim 19, Giesy teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle (12), and a shaft (20) having proximal and distal ends, the proximal end being connected to the handle (fig. 2) and the distal end including a substantially straight portion (20f) bent at an angle relative to an adjacent portion of the shaft (20c), wherein the substantially straight portion has a length that is less than about 10% of the entire length of the shaft.

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Regarding Claim 24, Giesy teaches the delivery device of claim 19, wherein the angle relative to the shaft is greater than about 90 degrees.

Regarding Claim 27, Giesy teaches the delivery device of claim 19, including a connector (20b) located at the distal end of the shaft for attaching to an end of the implant (40).

Regarding Claim 28, Anderson teaches the delivery device of claim 27, wherein the connector (20b) is formed integral to the shaft (20).

Regarding Claim 29, Giesy teaches the delivery device of claim 28, wherein the connector includes a slot (82) formed in the shaft.

Regarding Claim 30, Giesy teaches the delivery device of claim 28, wherein the slot extends from a surface of the shaft radially (82) into the shaft and axially in a distal direction (83) to form a substantially L- shape.

Regarding Claim 32, Giesy teaches the delivery device of claim 27, wherein the connector includes a receptacle (82) portion for interfitting with a mating connector on the end of the implant.

Regarding Claim 33, Giesy teaches a delivery system for delivering an implant to an anatomical site in a body of a patient, the system comprising, an implant (40) having first and second ends, and a delivery device comprising a handle (12), and a shaft (20) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length, the proximal end of the shaft being attached to the handle (fig. 2) wherein the distal end of the shaft includes a substantially straight portion (20f) bent at an angle

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relative to an adjacent portion (22c) of the shaft, and the substantially straight portion has a length that is less than about 10% of the entire length of the shaft.

Regarding Claim 42, Giesy teaches the delivery device of claim 33, wherein a most distal one of the plurality of curves includes a concave portion (20e) and a convex portion (20d) and the substantially straight portion bent at an angle is formed toward the concave portion (fig. 7).

Regarding Claim 47, Giesy teaches the delivery device of claim 33, including a connector (20b) located at the distal end of the shaft for attaching to an end of the implant (40).

Regarding Claim 48, Anderson teaches the delivery device of claim 47, wherein the connector (20b) is formed integral to the shaft (20).

Regarding Claim 49, Giesy teaches the delivery device of claim 48, wherein the connector includes a slot (82) formed in the shaft.

Regarding Claim 50, Giesy teaches the delivery device of claim 48, wherein the slot extends from a surface of the shaft radially (82) into the shaft and axially in a distal direction (83) to form a substantially L- shape.

Regarding Claim 52, Giesy teaches the delivery device of claim 47, wherein the connector includes a receptacle (82) portion for interfitting with a mating connector on the end of the implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 12, 13, 17, 19, 21, 26, 27, 31, 34, 35, 37, 40, 46, 47, 51, 53-55, 58-61 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Brenneman as a matter of design choice. Anderson teaches a method of delivering an implant to an anatomical site in a body comprising:

- inserting into a body of a patient a shaft having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length (fig. 4)
- attaching the distal end of the shaft to a first end of an implant (fig. 6), and positioning the implant at an anatomical site within the body of the patient (fig. 8)
- wherein the distal end of the shaft includes a substantially straight portion (58) bent at an angle relative to an adjacent portion of the shaft

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- inserting the shaft into the body of the patient suprapubically (fig. 4).
- inserting the shaft into the body of the patient suprapubically (fig. 4).
- wherein the implant includes a sling (46) with first and second ends for treating urinary incontinence and the method includes positioning the sling in a loop around a midurethral location (fig. 11) with the ends of the sling extending from the midurethral location along an anterior surface of the pubic bone of the patient.
- wherein the angle is determined to accommodate a pubic bone of a patient (fig. 11).
- wherein the handle and the shaft are reversibly attached (fig. 2).
- a connector (58) located at the distal end of the shaft for attaching to an end of the implant (46).
- the connector includes a plug portion (58) for interfitting with a receptacle (56) on the end of the implant.
- an implant (46) having first and second ends
- a delivery device comprising a handle (64), and a shaft (60) having proximal and distal ends and shaped to describe a plurality of curves substantially in a single plane along its length, the proximal end of the shaft being attached to the handle
- the implant includes a sling for treating urinary incontinence (Column 9, proximate lines 1-5).
- The sling is configured for placement at a midurethral anatomical site in the body of a patient (fig. 9)

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Anderson fails to disclose wherein the substantially straight portion has a length that is less than about 10% of the entire length of the shaft or wherein the shaft is introduced into the body of the patient prepubically or transobturally.

Regarding the limitation wherein the substantially straight portion has a length that is less than about 10% of the entire length of the shaft, Due to lack of criticality in the specification, it would have been an obvious matter of design choice to define the length of the distal straight section as being less than about 10% of the length of the shaft, since such a modification would have involved a mere change in size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose 105 USPQ 237 (CCPA 1955). Further it would be obvious to alter size of the distal straight section to accommodate different body sizes.

Regarding wherein the shaft is introduced into the body of the patient prepubically or transobturally, the application discloses wherein the same instrument is capable of performing each procedure and the applicant fails to disclose any advantage of using a prepubic or transobtural procedure rather than a suprapubic approach as disclosed by Anderson or transvaginal approach as taught by Brenneman. Since the applicant has not disclosed that these two methods provide any advantage over the suprapubic procedure, and the device of Anderson is capable of performing a transvaginal approach as taught by Brenneman, or prepubic or transobtural procedure to place a surgical implant at a midurethral area, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the procedure using the device

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transvaginally as disclosed by Brenneman, or prepubically or transobturally as a matter of design choice.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
10/26/06


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

10/28/06